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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,823

07/11/2005

Danuta Ciok

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09/12/2006

JACOBSON HOLMAN PLLC
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EXAMINER

HAND, MELANIE JO

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/541,823

Applicant(s)

CIOK ET AL.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/20/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgement is also made of applicant's claim for priority under 35 U.S.C. 371, which claims benefit of PCT/DK04/00011, filed on January 12, 2004.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 20, 2006 was filed after the mailing date of the Application on July 11, 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al (WO 98/53771).

With respect to **Claims 19,27,32**: Nielsen teaches an ostomy appliance comprising adhesive wafer 2 having first adhesive surface for securing the appliance to the user's skin and a second surface covered with carrier sheet 16. Wafer 2 has hole 3 for receiving a stoma. Sealing member 5 integral with wafer 2 comprises a hydrophobic adhesive compatible with the first adhesive surface 13 and allows adaptation of the size of hole 3 to accommodate a stoma by enlarging hole 3 by rolling up the rim of said hole to form torus 20. Torus 20 is locked in rolled up position by contact to the surface surrounding the stoma, specifically with the aid of flange 8 of sealing member 5.

With respect to **Claims 20,33,34**: As can be seen in Fig.7, the contact between first adhesive surface 13 (after release liner 15 is removed) and the second surface 7 locks torus 20 to the second surface in its rolled position.

With respect to **Claim 21,31**: Wafer 2 and sealing member adhesive 7 are each comprised of a hydrocolloid adhesive.

With respect to **Claim 22**: Carrier sheet 16 does not cover sealing member 5, therefore it is absent on a second part of the second surface surrounding the stoma.

With respect to **Claim 23**: Hydrophobic adhesive 7 stretches under the edge of carrier sheet 16.

With respect to **Claim 24**: Release liner 15 protects second adhesive surface 7.

With respect to **Claim 25**: Carrier sheet 16 adheres to flange 11 and extends beyond the inner rim of wafer 2 to the central part.

With respect to **Claim 28**: Wafer 2 has flange 11 that couples with flange 12 of receiving bag 4 (collectively, coupling means) for releasable attachment of said bag.

With respect to **Claim 29**: Flange 11 and flange 12 are matching coupling rings.

With respect to **Claim 30**: Nielsen teaches an ostomy appliance comprising adhesive wafer 2 having first adhesive surface for securing the appliance to the user's skin and a second surface covered with carrier sheet 16. Wafer 2 has hole 3 for receiving a stoma. Sealing member 5 integral with wafer 2 comprises a hydrophobic adhesive compatible with the first adhesive surface 13 and allows adaptation of the size of hole 3 to accommodate a stoma by enlarging hole 3 by rolling up the rim of said hole to form torus 20. Torus 20 is locked in rolled up position by contact to the surface surrounding the stoma, specifically with the aid of flange 8 of sealing member 5.

With respect to **Claim 35**: Sealing member 5 is comprised of a hydrocolloid adhesive.

With respect to **Claim 36**: Nielsen teaches an ostomy appliance comprising adhesive wafer 2 having first adhesive surface for securing the appliance to the user's skin and a second surface covered with carrier sheet 16. Wafer 2 has hole 3 for receiving a stoma. Sealing member 5 integral with wafer 2 comprises a hydrophobic adhesive compatible with the first adhesive surface 13 and allows adaptation of the size of hole 3 to accommodate a stoma by enlarging

hole 3 by rolling up the rim of said hole to form torus 20. Torus 20 is locked in rolled up position by contact to the surface surrounding the stoma, specifically with the aid of flange 8 of sealing member 5. The hole 3 is intended to accommodate a stoma and being placed at the location of a stoma on the patient, therefore Nielsen teaches the method steps set forth in claim 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al (WO 98/53771).

With respect to **Claim 26**: Sealing member 5 has grooves 21 that encircle the central hole 3 where the rim of said central hole is rolled up and enlarged in part by compressing said grooves. Nielsen does not explicitly teach that the release liner 15, which covers said grooves, is provided with a weakening pattern, however it would be obvious to one of ordinary skill in the art

to provide such a weakening pattern to allow liner 15 to bend with the sealing member to prevent premature rupturing of the release liner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH
September 2, 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

